EXHIBIT Y

ETHICON
a Johnson & Johnson company

January 19, 2005

Biocompatibility Risk Assessment for Gynecare PROLIFT Total Pelvic Floor Repair System

The Gynecare PROLIFT Total Pelvic Floor Repair System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect. Each system contains one or more of the following components:

1. Gynecare Gynemesh PS Mesh Implant[1]
2. Guide
3. Retrieval Device
4. Cannulas

A biocompatibility assessment plan was developed by CPC based on ISO 10993 Part One and FDA Blue Book General Program Memorandum G-95-1 guidelines. Table 1 summarizes the components and materials of the PROLIFT system[2] along with the type of patient contact. For biocompatibility testing purposes, component (1) was classified as an implant, while components (2), (3) and (4) were considered to be externally communicating, coming into contact with tissues for less than 24 hrs.

The Gynecare Gynemesh PS Mesh is the same as the mesh used in the Gynecare TVT Base and Gynecare TVT Obturator. Per ISO 10993 and FDA G-95 guidelines, no testing is required because equivalent material is being used in equivalent use.

For the externally communicating components, the following biological effects were evaluated in compliance with the FDA-GLP regulations:

1. Cytotoxicity (In vitro, MEM Elution assay)
2. Sensitization (In vivo, Guinea Pig, Magnusson and Kligman, Saline & Sesame Oil Extracts)
3. Intracutaneous reactivity (In vivo, Rabbit, Saline & Sesame Oil Extracts), and
4. Acute systemic toxicity (In vivo, Mouse, Saline & Sesame Oil Extracts).

The Biocompatibility results for the materials are summarized in Table 2. In all cases the results were acceptable. The Biocompatibility testing for Pebax 7033 and Pebax 4033 was done

1 The Gynecare Gynemesh PS mesh implant comes in three versions all made of the same material; (i) the anterior mesh implant used for anterior defect repair, (ii) the posterior mesh implant used for posterior defect repair and / or apical suspension, and (iii) The total mesh implant is used for combined anterior, apical and posterior defect repair.

2 Information provided by Project Leader Scott Ciarrocca. See attached memo.

on natural materials. The presence of the colorant titanium dioxide (2%) and plant-derived zinc stearate (0.5%) as mold release agent in these materials in the final device will be of no toxicological consequence as exposure of humans to these agents is quite common from medicines and food. Additionally, devices and materials containing titanium dioxide and zinc stearate have been tested successfully for biocompatibility[3].

The percent composition of 316LVM for the Guide Needles with respect to Si and Mn, is within the specifications of 316 stainless steel, a material approved for surgical instruments[4,5]. With regard to the percent composition of C, P, S, Cr and N, their content in 316LVM is less or equal to the percent composition of other austenitic stainless steels approved for surgical instruments[4]. The percent composition of Mo and Ni in 316LVM stainless steel exceeds the approved composition for austenitic stainless steels by 0.7 and 0.5 percent, respectively. It is not anticipated that this small difference will cause sensitization or any other adverse effects, as it is highly unlikely that significant amounts of these metals would be released from the device[6]. Similarly, the composition of 304V stainless steel for the coil wire in the Cannula tube is within the ranges of other austenitic stainless steels approved for surgical instruments[4].

The Prolene in the retrieval device is made of the same material as the Gynecare Gynemesh PS, the Gynecare TVT Base and the Gynecare TVT Obturator Meshes. However, the retrieval device is exposed to Cobalt-60 while the Gynecare Gynemesh PS is exposed to ethylene oxide. To account for the difference in the sterilization method, EO exposed and 45KGy irradiated retrieval devices were subjected to comparative analytical testing (IR and polar/non-polar extractables) to determine if there were any significant differences. No significant differences were observed[7]. Per ISO 10993 and FDA G-95 guidelines, no testing is required because equivalent material is being used.

The biocompatibility of Nusil MED-6015 was assessed with unsterilized material. To account for the lack of sterilization, EO exposed and non-exposed material samples were subjected to comparative analytical testing (IR and polar/non-polar extractables) to determine if there were any significant differences. No significant differences were observed[8]. Per ISO 10993 and FDA G-95 guidelines, no testing is required because equivalent material is being used.

The packaging materials are being used in currently marketed similar devices[9] and they do not come in direct contact with the patient.

Based on the biocompatibility data obtained on the component materials of the Gynecare PROLIFT Total Pelvic Floor Repair Systems, the use of these materials in the application described above is not considered to represent a significant risk to human health.

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3 e.g., Pebax 55D (M1095) 5F Infiniti Catheter (M1603), Vestamid 75D (M1402) (Biocompatibility Database Reference Number)

4 Information provided by Vincenza Zaddem. See attached email message from Zaddem to Pelekis dated Wed 7/28/2004.

5 ASTM Standard F 899-02. Standard Specification for Stainless Steels for Surgical Instruments.

6 See attached report from Tom Barbolt, dated July 15, 1996.

7 See attached Analytical Chemistry report (Service Request 44133).

8 See attached Analytical Chemistry report (Service Request 44146).

9 See attached memo from P. Komarnycky, dated January 3, 2005.

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Table 1: Components and materials of PROLIFT Systems

PICTURE	PART NO.	NAME	MATERIAL	PATIENT CONTACT
Mesh Implants				
	P19310 (Ethicon Sàrl)	Total Mesh Implant	Prolene, Polypropylene	Yes - Implant
Guide				
	R02-011-001-003 (Ruetschi Technologies AG)	Guide Needle Type A	AISI 316 LVM 1.4441 stainless steel, full hard	Yes - Tissue
	R02-011-001-001	Guide Handle sup Type A	Calibre Polycarbonate Color: White PC-2061-15-FC850122	Yes - Tissue
	R02-011-001-002 (Ruetschi Technologies AG)	Guide Handle inf Type A		
Cannula				
	Eth 01002 (MS Techniques)	Cannula Tube	Inner Liner and Tip: Pebax 7033 SA 01 (69D) Outer Jacket: Pebax 4033 SA01 Colorant: 2% Titanium Dioxide (White) Mold Release Agent: 0.5% Zinc Stearate (plant-derived) Wall Reinforcement: Inox 304 V stainless steel round wire coil	Yes - Tissue

Table 1 Cont'd

PICTURE	PART NO.	NAME	MATERIAL	PATIENT CONTACT
	4.04.711 (Gsell Engineering Plastics AG)	Cannula Hub	Pebax 4033 SA 01 Colorant: 2% Titanium Dioxide (White)	Yes - Tissue
Retrieval Device				
	D0380201 (Medi-Line SA)	Retrieval Line – Shrink Tube	Altera medical-grade, USP Class VI, flexible, polyolefin tubing Color: Natural	Yes - Tissue
	D0380202 (Medi-Line SA)	Retrieval Line –Monofilament	Prolene, Polypropylene Blue Resin	Yes - Tissue
N/A	Datasheet MED-6015 10 September 2004 (Nusil Technologies)	Sealant	MED-6015	Yes – Tissue
Packaging				
N/A	50-C-1650 (Ethicon Inc)	E-Pack/Peel Pouch Design Overwrap Pouch 10"	Tyvek/Copolymer Pouch 10.00" x 18.375	No
N/A	DGPF 001 (Ethicon Inc)	D'Art Guide Paper Folder	12 pt Suture Board	No
N/A	P19025 (Mangar Industries, Inc)	Polymer Implant Pouch	Tyvek/Film Top Layer:M1811 film Bottom Layeer: Uncoated 1073B Tyvek	No

Table 2: Summary of Biocompatibility Test Data

	Test Category	Title	Accession No	Result
1.		**Calibre 2061-15, White FC850122**		
	Cytotoxicity	Cytotoxicity - Elution Assay	15B-1	Passed
	Sensitization	Maximization Sensitization Test (ISO)	16G-13	Passed
	Intracutaneous irritation	USP Intracutaneous Test	16E-05	Passed
	Acute systemic toxicity	USP Systemic Injection Test	16E002	Passed
	Acute systemic toxicity	USP Rabbit Pyrogen Test	16E-02	Passed
2.		**Natvar Pebax 7033 SA 01 Polyether Polyamide Copolymer**		
	Cytotoxicity	Cytotoxicity - Elution Assay	V8E081G	Passed
	Sensitization	Maximization Sensitization Test (ISO)	X9D359G	Passed
	Intracutaneous irritation	USP Intracutaneous Test	X9D356G	Passed
	Acute systemic toxicity	USP Systemic Injection Test	X9D357G	Passed
	Acute systemic toxicity	USP Rabbit Pyrogen Test	X9D358G	Passed
3.		**Pebax 4033 SA 01 (Atofina/Putnam)**		
	Cytotoxicity	Cytotoxicity Study Using 1X MEM Extract	PSE 04-0529	Passed
	Sensitization	ISO Maximization Sensitization Study using Saline and Sesame Seed Oil Extracts	PSE 04-0530	Passed
	Intracutaneous irritation	ISO Intracutaneous Reactivity Test in Rabbits using Saline and Sesame Seed Oil Extracts	PSE 04-0531	Passed
	Acute systemic toxicity	USP and ISO Systemic Toxicity Study using Saline and Sesame Seed Oil Extracts	PSE 04-0532	Passed
	Acute systemic toxicity	Material Mediated Pyrogenicity using a Saline Extract	PSE 04-0533	Passed
4.		**Altera MT5000 RT 145 Polyolefin black shrink tubing**		
	Cytotoxicity	Cytotoxicity – Elution Test	V5A122G	Passed
	Sensitization	Delayed Contact Sensitization Study (A Maximization Method) in theGuinea Pig Study (Saline and CottonSeed Oil Extracts)	TA006-300	Passed
	Intracutaneous irritation	USP Intracutaneous Toxicity Study in the Rabbit (Extracts)	TU013-800	Passed
	Acute systemic toxicity	USP Systemic Injection	X5A188G	Passed
	Acute systemic toxicity	Rabbit Pyrogen Study – Material Mediated	TU010-807	Passed

Table 2: Cont'd

5.	MED-6015			
	Cytotoxicity	Cytotoxicity Assessment Using the ISO MEM Elution Assay	PSE 03-0242	Passed
	Sensitization	Guinea Pig Maximization Study using Saline and Sesame Seed Oil Extracts	PSE 03-243	Passed
	Intracutaneous irritation	Intracutaneous Reactivity Test using Saline and Sesame Seed Oil Extracts	PSE 03-0244	Passed
	Acute systemic toxicity	Acute Systemic Toxicity Test in Mice using Saline and Sesame Seed Oil Extracts	PSE 03-0245	Passed

ETH-03897